Remarks

By this amendment, the applicants seek to place the present application in a form more suited to examination in the United States Patent and Trademark Office. Specifically, the applicants seek to introduce into the specification specific language supporting claim 29. This has been accomplished by introducing the underlined portion of the paragraph bridging pages 14 and 15 of the specification as reproduced below:

Monitoring the control area enables an earlier detection of the presence of sample liquid in the control area than when measuring in the detection area. When liquid is detected a signal can be emitted which terminates supply of sample liquid. The signal can be an optical and/or an acoustic signal. In the case of a capillary gap test element this for example means that blood supply to the capillary gap can be terminated. Consequently it is possible to prevent unnecessary supply of further sample liquid and thus to reduce the required amount of sample and on the other hand this procedure shortens the time required to supply sample liquid which is convenient for the user. Nevertheless the method according to the invention still ensures that the detection area or detection areas of the detection zone are adequately supplied with sample liquid. For this purpose it is advantageous when the detection area is nearer than the control area to the first zone which firstly comes into contact with the sample liquid. Thus the test element is wetted with sample liquid in the area of the detection zone earlier than in the area of the control zone and when sample liquid is present in the area of the control zone it is ensured that the detection zone is also supplied with sample liquid. According to the invention it is also preferred that the control area (area A in figure 6) is irradiated with radiation that is absorbed by the sample liquid itself. Even if the sample liquid does not itself absorb radiation or only partially absorbs radiation there is usually a decrease in the reflected or transmitted radiation when the control zone is moistened. As a result the presence of sample liquid can already be determined before a reaction with reagents has taken place in the detection zone. Figure 7 shows that a decrease in reflection in area A of the detection zone shown in figure 6 is already found in the time interval II. This is due to the fact that a

thorough moistening of the control area A can be very rapidly detected by a 880 nm light-emitting diode. Detection of a wetting of this area on the basis of a colour formed in the detection zone would not have been possible until time interval IV. In the method according to the invention in which sample application is detected, the control area is preferably on the detection zone. This not only reduces the time until detection but also allows a compact construction of such an instrument in which the optical components can be in close vicinity to one another.

The applicants also seek to remove any improper multiple dependency from the claims. The applicants also seek to more accurately reflect the sense of the invention through the selection of terminology and positive recitation of steps and elements, as well as through careful attention to antecedents throughout the claims. The actual changes in the claims can be seen from the following reproduction of the restated claims wherein the added text is underlined and the deleted text is bracketed.

1. (Amended) A method [Method] for the photometric analysis of test elements having [with] a detection zone, the method being tolerant of [which is stable towards] positioning variations [tolerances] of the detection zone, comprising the steps of

a) placing a test element in a holder such that the detection zone of the test element is positioned relative to an illumination unit having a [with at least one] first and a second light source, a positioning variation [tolerance] of the detection zone occurring in at least one direction,

b) contacting [a sample with] the detection zone with a sample such that a detection system present in the detection zone leads to a photometrically detectable change in the detection zone when an analyte is present in the sample,

c) activating the first light source to irradiate a first region of the detection zone, and detecting at least one of [the] light reflected from the detection zone or light transmitted through the detection zone, in order to generate a first detection signal,

d) activating the second light source to irradiate a second region of the detection zone which is displaced relative to the first region in the direction of the positioning variation [tolerance] and detecting at least one of [the] light reflected from the detection zone or light transmitted through the detection zone in order to generate a second detection signal,

e) comparing the first and the second detection signal and determining whether the first and/or the second detection signal has been obtained by illuminating an area situated completely on the detection zone and selecting the corresponding detection signal, and

f) determining the analyte concentration contained in the sample by analysing the selected detection signal.

2. (Amended) A method [Method] as claimed in claim 1, wherein the detection signal that has a lower intensity is selected.

3. (Amended) A method [Method] as claimed in claim 1, further comprising the steps of:

g) determining [wherein appropriate steps are carried out in steps c) and d) before the detection zone is contacted with the sample according to step b) in order to determine] a first and a second base-line detection signal on an unused test element, and

h)standardizing [wherein] the first and the second detection signal [are standardized] by division by the corresponding base-line detection signal before determining the analyte concentration in step f).

4. (Amended) A method [Method] as claimed in claim 1, wherein the first region irradiated by the first light source and the second region irradiated by the second light source have essentially the same size.

5. (Amended) A method [Method] as claimed in claim 1, wherein the test element is a capillary gap test element.

6. (Amended) A method [Method] as claimed in claim 1, further comprising the step of: arranging [wherein the detection zone has a width X and] the first and second light source [are arranged] such that focal points of the light sources are located in a connecting line [between the focal points of the regions irradiated by the light sources runs] running essentially parallel to the width X of the detection zone.

7. (Amended) A method [Method] as claimed in claim [claims 5 and] 6, wherein the test element is a capillary gap test element containing a capillary gap, and the width X is arranged essentially perpendicular to the capillary gap.

8. (Amended) A method [Method] as claimed in claim [claims] 1 [or 5], wherein the regions [region] irradiated by the first light source and [the region irradiated] by the second light source are ovals.

9. (Amended) A method [Method] as claimed in claim [claims] 1 [or 5], wherein the regions [region] irradiated by the first light source and [the region irradiated] by the second light source are rectangles.

10. (Amended) A method [Method] as claimed in claims 1, 8 or 9, wherein the first and second irradiated regions overlap.

11. (Amended) A method [Method] as claimed in claim 10, wherein the maximum overlap is less than half the diameter of the irradiated regions.

12. (Amended) A method [Method] as claimed in claim 6 [1], wherein the [detection zone has a width X and a connecting line between the first region and second [irradiated] region is arranged essentially parallel to the width X, the] first region [irradiated by the first light source] has a width d1 and the second region

[irradiated by the second light source] has a width d2, and the first and second [irradiated] regions overlap over a maximum width "a" in the direction of the connecting line whereby the following applies:

$d1 + d2 - a < X$.

13. (Amended) A method [Method] as claimed in claim 12, in which the following applies:

$a<(d1 + d2)/2$.

14. (Amended) A method [Method] as claimed in claim 1, [wherein the illumination unit has] further comprising the steps of:

a) activating at least one further light source which irradiates a third region and

b) detecting a change in at least one of [the irradiation] reflected or transmitted light from the third region [is detected in order] to detect the presence of the sample.

15. (Amended) A method [Method] as claimed in claim 14, wherein the at least one further [additional] light source emits radiation in a second wavelength range that is different from that of the first and second [at least two] light sources and radiation [transmitted or reflected] in this second wavelength is detected in order to detect the presence of sample.

16. (Amended) A method [Method] as claimed in claim 15, wherein the second wavelength range is in the range of 800 to 950 nm.

17. (Amended) A method [Method] as claimed in claim 14, wherein the third region is located on the detection zone.

18. (Amended) A method [Method] as claimed in claim 17, wherein the sample is brought into flow contact with the detection zone and the third region is located downstream of the first and second region.

19. (Amended) A device [Device] for the photometric analysis of test elements comprising:

- an illumination unit comprising at least a first and a second light source,
- a holder for holding a test element with a detection zone in such a manner that the detection zone is positioned relative to the illumination unit,
- [a detection unit with at least one detector which detects light reflected from the detection zone or transmitted through the detection zone,]
- a control unit which activates the first light source during a first activation phase in order to illuminate a first region of the detection zone and activates the second light source during a second activation phase in order to illuminate a second region of the detection zone, [and]
- a detection unit with at least one detector which detects light reflected from the detection zone or transmitted through the detection zone, the signal generated by the detection unit during the first activation phase [is] being recorded as the first detection signal and the signal generated during the second activation phase [is] being recorded as the second detection signal,
- an analytical unit which compares the first and second detection signal and determines whether the first and/or the second detection signal has been obtained by illuminating a region situated completely on the detection zone, and analyses a corresponding analyte detection signal [is analysed] in order to determine an analyte concentration in a sample.

20. (Amended) A device [Device] as claimed in claim 19, wherein the illumination unit has at least one additional third light source which emits radiation in a second wavelength range that is different from the first and second [at least two] light sources and radiation transmitted or reflected in this second wavelength range is detected.

21. (Amended) A device [Device] as claimed in claim 20, wherein the second wavelength range is 800 to 950 nm.

22. (Amended) A device [Device] as claimed in claim 20, wherein the third light source irradiates a region of the detection zone which does not overlap with the first and second regions [illuminated region].

23. (Amended) A method [Method] for the photometric analysis of a test element with detection of sample application on a flat detection zone of the test element comprising the steps

- irradiating a control region of the detection zone,
- supplying sample liquid to the detection zone in such a manner that a first zone of the detection zone comes into contact with sample liquid earlier than a second zone which is laterally displaced from the first zone,
- monitoring [the] radiation reflected from the control zone or transmitted through the control zone,
- detecting presence of the sample liquid in the control region from [as a result of] a change of the reflected or transmitted radiation,
- irradiating [irradiation of] at least one detection region of the detection zone, wherein the detection region is nearer to the first zone than the control region,
- detecting radiation [which has been] reflected from [the detection region] or transmitted through the detection region,
- generating a signal that can be recognized by a user of the test element to terminate supply of sample liquid when the presence of sample liquid is detected in the control region, and
- analysing the detected radiation to determine the concentration of an analyte in the sample liquid.

[wherein

when the presence of sample liquid is detected in the control region a signal that can be recognized by the user is generated so that the supply of sample liquid can be terminated.]

24. (Amended) A method [Method] as claimed in claim 23, wherein the test element includes [is] a capillary gap [test element].

25. (Amended) A method [Method] as claimed in claim 24, wherein the capillary gap runs below the detection zone.

26. (Amended) A method [Method] as claimed in claim 23, wherein the detection region is nearer to the first zone than the control region.

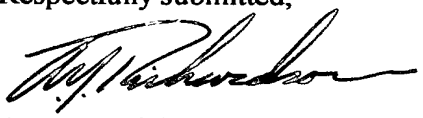
27. (Amended) A method [Method] as claimed in claim 23, wherein the control region is irradiated with radiation that is absorbed by the sample liquid.

28. (Amended) A method [Method] as claimed in claims 23 or 27, wherein the detection region is irradiated with radiation that is essentially not absorbed by sample liquid.

29. (Amended) A method [Method] as claimed in claim 23, wherein the signal that can be recognized by a user is an optical and/or an acoustic signal.

Applicants submit that with the forgoing amendments, the present application satisfies all requirements for grant of a patent, and allowance of the present application is respectfully requested.

Respectfully submitted,



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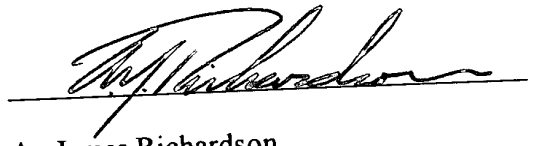

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